(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 3 February 2005 (03.02.2005)

(10) International Publication Number WO 2005/009356 A3

(51) International Patent Classification⁷: A61K 47/30, 09/50

A61F 02/02.

(21) International Application Number:

PCT/US2004/022816

(22) International Filing Date: 15 July 2004 (15.07.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/487,663

15 July 2003 (15.07.2003) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:

US Filed on

60/487,663 (CON) 15 July 2003 (15.07.2003)

(71) Applicant (for all designated States except US): PR PHARMACEUTICALS [US/US]; 1716 Heath Parkway, Fort Collins, CO 80522 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): GARY, P., Cook [US/US]; 1426 S. Bowen St., Longmont, CO 80501 (US).

(74) Agent: MCCALLUM, Jennifer, M.; The McCallum Law Firm, LLC, 132 Kolar Ct., Erie, CO 80516 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN. CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW. (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS. JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA. SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, F1, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations
- of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 9 June 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD FOR THE PREPARATION OF CONTROLLED RELEASE FORMULATIONS

(57) Abstract: The methods disclosed herein are of use for the production of controlled release compositions. In particular, the methods provide the contacting of an organic phase containing a bioactive agent and a polymer with an aqueous phase containing an organic ion to create controlled release compositions containing bioactive agents. The present invention also includes controlled release compositions including a polymer, an organic ion and a bioactive agent. The present invention also includes methods of using such controlled release compositions. The usefulness of the present invention is that the methods result in the production of controlled release compositions containing bioactive agent capable of administration in a concentrated low-dose form, having low burst and reduced production of degraded bioactive agent.



